

**Docket No. 02N-0204**

**Bar Code Label Requirements  
for Human Drug Products  
Public Meeting (2002 July 26)**

**Perspective of the Vaccine Identification Standards Initiative (VISI)**

Comments (revised 2002 Aug 2) presented by

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I thank the Food and Drug Administration for this opportunity to comment on the issue of mandating identifying barcodes on primary pharmaceutical packaging. For the past several years, I have coordinated the **Vaccine Identification Standards Initiative**, known as “VISI”, which is a collaborative effort by a variety of public health agencies and private organizations and groups involved in the practice of immunization, including medical and nursing associations and the vaccine industry itself. Full information about VISI and its recommendations regarding barcodes and packaging are available at its website: <http://www.cdc.gov/nip/visi>

The purpose of VISI is to establish voluntary, uniform guidelines for the packaging and labeling of vaccines and the recording of their identifying information. The goal is to improve the accuracy and convenience of transferring vaccine information into medical records and immunization registries, and thus to enhance the monitoring of immunization programs and the surveillance for adverse events of vaccination.

The National Childhood Vaccine Injury Act of 1986 mandates that all persons who administer recommended childhood vaccines must record the vaccine identity and lot number in the medical record.\* However, evidence from the Vaccine Adverse Event Reporting System

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\* Public Health Service Act, Title 42, Chapter 6A, Subchapter XIX, Part 2, subpart c  
(<http://www.fda.gov/opacom/laws/phsvcact/300aa-25.htm>)

(VAERS, <http://www.vaers.org/>), which CDC runs jointly with FDA, suggest that from 10 to 20 percent of medical records lack these mandated lot numbers. CDC's separate Vaccine Safety Datalink project<sup>†</sup> monitors the vaccination and medical experience of a cohort of 2-½ percent of the U.S. population through a network of health maintenance organizations (HMOs). It reveals a similarly high frequency of non-existent lot numbers and ambiguous vaccine identities, probably as a result of transcription errors and handwriting ambiguity.

Among the six major recommendations of VISI, the first is for vaccine vials and prefilled syringes to have reduced-size symbology ("RSS") barcoding containing the National Drug Code (NDC), expiration date, and lot number on vials and on duplicate or triplicate peel-off stickers. This information could then be readily captured into medical records and other forms, either electronically or by old-fashioned peeling off and pasting. Photographs illustrating prototype samples of multiple peel-off stickers and RSS barcoding on vaccine vials are shown at the bottom of this document.

A barcode with the NDC can be preprinted relatively easily on long rolls of label stock, which are applied onto vials or other primary containers (e.g., prefilled syringes) at the time when vaccines or other drugs are filled into unit-of-use containers from the bulk batches in which they are manufactured. Such printing usually occurs at separate printing shops or by outside contractors well in advance of the filling process. Printing a barcode with the NDC would thus require little or no adjustment to the carefully monitored and regulated vaccine filling lines.

However, lot numbers are often specific to identify each separate day of filling from a bulk batch. Thus, such numbers and their corresponding expiration dates cannot easily be preprinted on the label stock. They are usually printed on label stock just seconds before the label is attached to the filled and closed vial or other primary packaging during the filling process – "online" in industry parlance. Thus, printing barcodes encoding lot number and expiration date would require changes in filling-line printing equipment, along with modifications to the

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<sup>†</sup> Chen RT, Glasser J, Rhodes P, et al. The Vaccine Safety Datalink project: a new tool for improving vaccine safety monitoring in the United States. *Pediatrics* 1997;99:765-73.

associated scanning equipment. These scanners now verify the accuracy of the online printing of human-readable lot number and expiration dates, and would thus need to verify the additional barcodes as the labels pass before them.

Through consultations with experts in label printing technology, VISI has learned and witnessed demonstrations of recent advances that make the VISI label and sticker recommendation feasible today. This new technology includes labels with multiple layers and peel-off stickers (demonstration: <ftp://ftp.cdc.gov/pub/Data/NIP/MultiStickerRSSLabels-Schreiner.mov> [13Mb]; requires free QuickTime movie software: <http://www.apple.com/quicktime/download/>). In addition, new high-speed, high-resolution printers can produce RSS barcodes onto labels at the time of vial filling at the current rate of approximately 300 labels per minute. Newer, very fast vaccine filling lines with even higher speeds may require the use of two or more printers to service each such line.

Laser scanners capable of reading RSS barcodes have been available for several years from several vendors: [http://www.symbol.com/products/barcode\\_scanners/barcode\\_handheld\\_m2000.html](http://www.symbol.com/products/barcode_scanners/barcode_handheld_m2000.html) ([http://www.hhp.com/hhp/files/sellsheets/3800PDF-SS\\_Rev\\_D.pdf](http://www.hhp.com/hhp/files/sellsheets/3800PDF-SS_Rev_D.pdf)).

They are also in development from many others:

[http://www.uc-council.org/rss14/rss\\_vendor\\_information.htm](http://www.uc-council.org/rss14/rss_vendor_information.htm)

Street prices currently range from \$300 - \$500 each:

<http://www.barcodediscount.com/catalog/welch-allyn/imageteam-3800-3900.htm>

<http://www.barcodediscount.com/cgi-bin/r.pl?FILE=parts.htm;modelid=701>

In addition to **full barcoding on vial labels and their peel-off stickers**, described above, the remaining five components recommended by VISI include:

2. **Full bar coding on the vaccine's outer cardboard carton** (secondary packaging) of the National Drug Code, the expiration date, and the lot number (<http://www.cdc.gov/nip/visi/prototypes/RSS-PMC-API-HIB.pdf>). (Only the NDC is routinely barcoded now, principally because the National Wholesale Druggists Association insisted on it from industry several years ago.)

3. A **uniform vaccine administration record form** to receive the peel-off stickers for non-computerized medical practices (<http://www.cdc.gov/nip/visi/prototypes/UVARform.pdf>)
4. A user-friendly **database of vaccine National Drug Codes** on the web to assist software developers and others to identify vaccines from their NDC, and vice versa (<http://www.cdc.gov/nip/visi/ndcsearch/ndcsearch.htm>), and in the future to permit equivalency tables for conversion to other coding systems like CPT<sup>®</sup> and HL7.
5. A ***Vaccine Facts* information sidebar** on outer cardboard packaging, in order to standardize the format and location of key information for safe administration, as FDA has mandated with its highly-appreciated *Nutrition Facts* sidebars on foods (<http://www.cdc.gov/nip/visi/prototypes/vaccinefacts.pdf>).
6. **Standardized abbreviations for vaccine types and vaccine manufacturers** to save “real estate” on small peel-off stickers on vaccine vials (<http://www.cdc.gov/nip/visi/prototypes.htm#abbreviations>).

We would particularly urge FDA, in mandating barcodes on unit-of-use packaging, to specify the use of numbering systems and reduced-size, 2-dimensional, barcoding symbologies promulgated by the EAN.UCC (<http://www.ean-ucc.org/>), an international collaboration of non-profit standards organizations (<http://www.ean-int.org> , <http://www.uc-council.org> ) which already set guidelines for the existing barcodes we now see on pharmaceuticals, foods, and most other products in global commerce, and have developed new ones for small packages (<http://www.uc-council.org/rss14/> , [http://www.uc-council.org/documents/pdf/Microsoft\\_Word\\_-\\_HC-GL\\_May\\_2\\_2002\\_1.30.pdf](http://www.uc-council.org/documents/pdf/Microsoft_Word_-_HC-GL_May_2_2002_1.30.pdf)). This would avoid the headaches and confusion of a balkanized system, in which manufacturers might use diverse or ad hoc numbering systems or barcode symbologies. This could result in much extra work and expense if hospitals and clinics were thus required to set up customized systems to read them all, rather than use off-the-shelf hardware and software. It is better to use an existing global identification numbering standard already at work in many U.S. hospital receiving docks, warehouses, and pharmacies.

We would also strongly urge that both expiration date and lot number are essential data fields for both future bedside assurance systems, as well as for existing national drug and vaccine adverse events surveillance systems. Avoiding medical errors is not just a simple matter of

putting new technology at the bedside. It requires a systems approach, so that near-mistakes in “almost administering” an expired and recalled drug can be recognized, analyzed, and investigated to identify how the mistake almost occurred, and further reduce the risk of repetition.

Thank you.

(see **Illustrations**: next two pages)

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**Content of Reduced Size Symbology-Composite Symbology  
(RSS-CS) barcodes in VISI illustration 1 shown on next page.**

**1. Unparsed content:**‡ 01003999999999911704123110ABCDEF123456

**2. Parsed content:**

01 = Application Identifier for 14-digit global trade identification number (GTIN, formerly referred to as “EAN.UCC-14”)

0 = *Packaging Indicator* for unit-of-use package [first digit of GTIN]

03 = *EAN.UCC System Character* for U.S. pharmaceutical products in which the next 10 digits will be the National Drug Code [second string of GTIN]

9999999999 = National Drug Code [third string of GTIN]

1 = Check Character which verifies by algorithm the accuracy of the previous 13 characters in the GTIN [final character of GTIN]

17 = Application Identifier for 6-digit expiration date in the format YYMMDD (may use “00” for DD field when indicating only year and month)

041231 = expiration date of 2004 December 31

10 = Application Identifier (AI) for batch or lot number of variable length up to 20 alphanumeric characters (If not the final data string in the barcode, such as when appending a serial number, use the AI of “23” plus a digit to indicate the exact length of the batch or lot number which follows)

ABCDEF123456 = lot number

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‡ Entered by a laser scanner, not a keyboard, into this document. For clarity, the scanner was programmed to filter out various function and code characters which communicate information needed by the scanner to read the barcode. Function characters separate various data strings, while control codes identify the type of barcode being read, which may be used by software when different code types are to be read. See: [http://www.uncouncil.org/documents/pdf/Microsoft\\_Word\\_-\\_HC-GL\\_May\\_2\\_2002\\_1.30.pdf](http://www.uncouncil.org/documents/pdf/Microsoft_Word_-_HC-GL_May_2_2002_1.30.pdf).



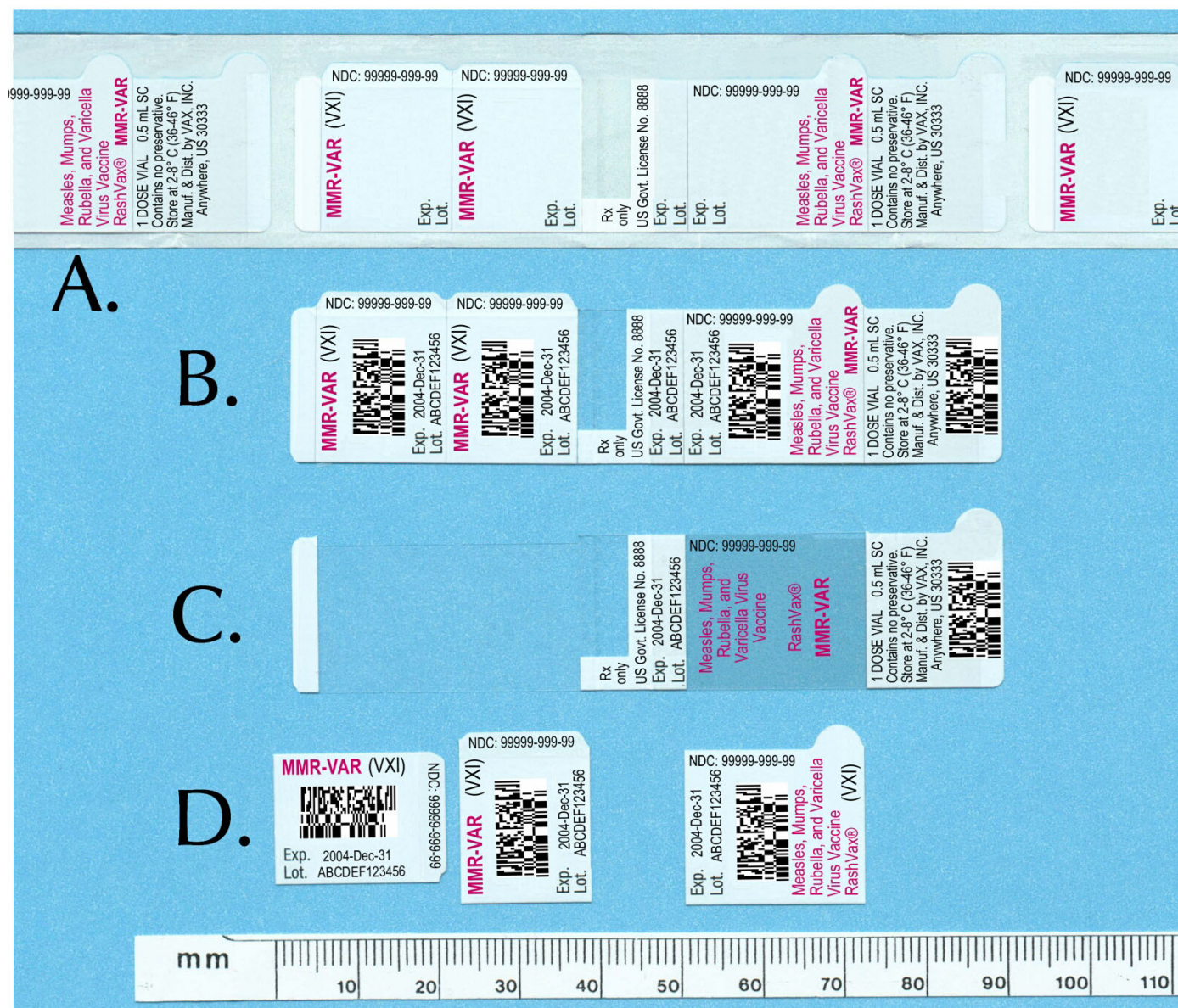
**VISI illustration 1.** Mock vaccine label illustrating multiple layers and triplicate peel-off stickers. (Label stock courtesy of Schreiner GmbH & Co.KG [<http://www.schreiner-etiketten.de>].)

Row **A.** Consecutive labels on a roll of release paper, pre-printed with NDC only.

Row **B.** Single label removed from roll, showing the online printing of RSS composite barcode with National Drug Code (NDC), lot number, and expiration date. When the label is unwrapped, two of the three peel-off stickers on the left are covered by the right-hand end of the label. The fourth barcode (at right) remains on permanent label which remains affixed to vial. To expose the detachable stickers, the peel-tab at the extreme right end of the label is pulled and the permanent label is unwrapped from the right. Its opposite end remains permanently affixed to vial. The permanent label can be reattached fully to the vial by rewrapping it.

Row **C.** Appearance of the unwrapped permanent label after removal of the three triplicate peel-off stickers. Vaccine identifying information which was printed on the 3<sup>rd</sup>-from-the-left peel off sticker is duplicated on the permanent label underneath this sticker.

Row **D.** The triplicate stickers peeled off.

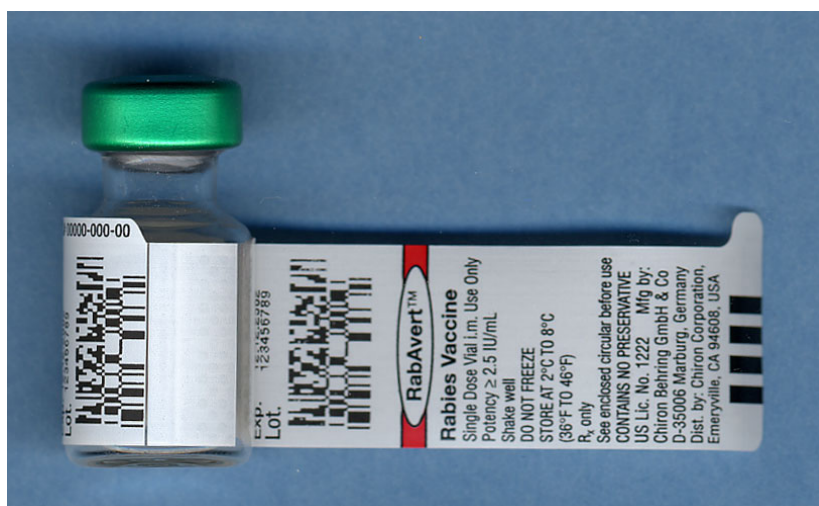


**VISI illustration 2.** Demonstration label for RabAvert™ vaccine applied to a vial (label courtesy of Chiron Vaccines [<http://www.chiron.com>] and Schreiner GmbH & Co.KG).

**Top Photo.** Wraparound label is closed. Imprinting of RSS barcode embedding National Drug Code, lot number, and expiration date is visible on permanent wraparound label. On the opposite side of label (not shown) is a transparent window to view clearly the vial contents.



**Middle Photo.** Wraparound label is unwrapped from the vial by peeling the tab visible on the upper right corner. Left side of label is permanently glued to vial. One of two duplicate, peel-off stickers with RSS barcode and human readable information -- formerly covered by wraparound label -- is now exposed on the vial.



**Bottom Photo.** Rear view of wraparound label unwrapped from the vial. Both duplicate, peel-off stickers -- formerly hidden underneath wraparound label -- are now visible on the vial.

